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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,133	03/01/2007	Shevchenko Natalya Michailovna	059-490-5030	1945
9629 7590 01/05/2009 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				
EXAMINER HOFFMAN, SUSAN COE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,133

Applicant(s)

MICHAILOVNA ET AL.

Examiner

Susan Coe Hoffman

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 3/07; 1/06
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed October 20, 2008 has been received and entered.
2. Claims 22-24 have been added in this amendment.
3. Claims 1-20 and 22-24 are currently pending.

Election/Restrictions

4. Applicant's election of Group I, now claims 1-18 and 22-24, ethanol for species A, *Fucus evanescens* for species B, sodium hydroxide for species C and sodium bicarbonate for species D in the reply filed on October 20, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The election of species for categories B, C, and D are withdrawn because the claims which contain these Markush groups depend from claims which are considered to be free of the art (see paragraph 19 below).

5. Claims 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
6. Claims 1-18 and 22-24 are examined on the merits.

Specification

7. The disclosure is objected to because of the following informalities: the disclosure lacks a brief description of the drawings.

Appropriate correction is required.

Claim Objections

8. Claims 2-17 and 22-24 are objected to because of the following informalities: the claims should begin with "The method" rather than "A method" because they are dependent method claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1, step iii, is indefinite because it is unclear what molecular weights are encompassed by "low molecular weights."

Claim 1 is also indefinite because step v states that the first extract is optionally concentrated. Step vi then states "the resulting concentrated extract" is further processed. It is unclear if step vi is optional and depends on if optional step v is carried out. If step vi is not optional, then the use of "the resulting concentrated extract" is unclear because step v would no longer be optional. Without carrying out step v, the claim does not produce a concentrated extract for processing in step vi.

10. Claim 2 is indefinite because the phrase "separating the fucoidan and laminaran" is unclear. It is unclear if this phrase indicates that fucoidan and laminaran are separated from each other or are both separated together from the ethanolic solution.
11. Claim 3 is indefinite because it states that 400 degree Celsius water is used to extract the seaweed residue. However, at this high temperature, water would be steam instead of liquid.
12. Claim 7 is indefinite because it states that a "second polysaccharide fraction" is obtained. Claim 4 has already specified that a "second polysaccharide fraction" has been produced. It is confusing to use the same terminology to refer to two apparently different fractions.
13. Claim 12 is indefinite because it is unclear what characteristics the seaweed must possess in order to be considered "fresh."
14. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 14 and 15 recite the broad recitations "pH of about 0.5-3.0" and "pH of about 2.0-5.0", respectively, and the claims also

recite "preferably 0.5-1.5" and "preferably 3.5-4.0", respectively, which are the narrower statements of the ranges/limitations.

15. Claim 16 is indefinite because it is unclear where the ultrafiltration step is carried out during the method steps set forth in the previous claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-4, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhuang et al. (Biosci. Biotech. Biochem (1995), vol. 4, pp. 563-567) in view of Nagumo et al. ("Fucan Sulfates and Their Anticoagulant Activities," Polysaccharides in Medicine Applications, (ed. S. Dumitriu), 1996, pp. 545-574).

Figure 3 in Zhuang teaches a method of extracting polysaccharides such as fucoidan from seaweed. The seaweed is first extracted with ethanol and separated to form a filtrate and Residue I. Residue I is further processed to form Residue II. This corresponds to step i and step ii in applicant's claim 1 where the filtrate corresponds to applicant's "alcoholic fraction" and Residue II corresponds to applicant's "first seaweed residue."

Figure 3 then shows that the filtrate (equivalent to applicant's "alcoholic fraction") is concentrated to form fraction "GS." Page 565, first paragraph, states that "GS" contains low molecular weight compounds. This corresponds to applicant's step iii in claim 1.

Figure 3 then shows that Residue II (equivalent to applicant's "first seaweed residue") is extracted under acidic conditions with hydrochloric acid. The reference does not specifically teach the pH of the acidic solution used in the extraction. However, Nagumo teaches that the yield of fucans (fucoidan) from seaweed is dependent on the pH of the extraction medium (see page 547). Thus, the art acknowledges that pH is a result effective variable that can be optimized in order to achieve the maximum extraction of fucans from seaweed. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, an artisan would have been motivated to optimize the pH of the hydrochloric acid solution used in this step of the extract taught by Zhuang. This optimization would lead to a step in Zhuang that is equivalent to applicant's step iv in claim 1 and claim 14.

After the acidic extraction, Zhuang separates the solution into a filtrate and Residue III. The filtrate corresponds to applicant's "aqueous first extract," and "Residue III" corresponds to applicant's "second seaweed residue."

Figure 3 then shows that the filtrate (corresponding to applicant's "aqueous first extract") is concentrated and precipitated with ethanol to form a polysaccharide fraction that corresponds to applicant's "first polysaccharide fraction". The reference does not teach the pH of the solution used to precipitate. However, as discussed above, Nagumo teaches that pH is a result effective variable. Thus, an artisan would have been motivated to optimize the pH of the solution used to precipitate the polysaccharide fraction in order to maximize the polysaccharide yield. Therefore, Zhuang also teaches applicant's step v and vi in claim 1 and claim 2. The reference does not specifically teach that this fraction contains laminaran and fucoidan. However, since the reference teaches the same steps as applicant, the reference product would naturally have to contain these polysaccharides if applicant's invention functions as claimed.

Figure 4 in Zhuang teaches extracting Residue III (corresponding to applicant's "second seaweed residue"). The reference does not specifically teach using water with the pH and temperatures claimed as the extraction solvent. However, Nagumo teaches using water to extract polysaccharides from seaweed and also teaches that the temperature and pH of the water are result effective variables (see page 547). Thus, an artisan of ordinary skill would have reasonably expected that acidic water could have been used successfully in the extraction of polysaccharides taught by Zhuang. The artisan would also have been motivated to optimize the pH and the temperature of the water in order to achieve the maximum extraction of the polysaccharides. After the extraction, Zhuang teaches separating the solution in a filtrate and

Residue IV. The filtrate corresponds to applicant's "aqueous second extract," and Residue IV corresponds to applicant's "third seaweed residue." Thus, Zhuang teaches steps that correspond to applicant's claims 3 and 15.

Zhuang then teaches concentrating and then drying the filtrate (corresponding to applicant's "aqueous second extract"). This step corresponds to applicant's claim 4. The reference does not specifically teach that this fraction contains polymannuronic acid, laminaran and fucoidan. However, since the reference teaches the same steps as applicant, the reference product would naturally have to contain these polysaccharides if applicant's invention functions as claimed.

17. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhuang and Nagumo as applied to claims 1-4, 14, and 15 above, and further in view of Sakai (WO 02/086116 - US 7,041,656 is the translation of WO '116, for ease US '656 will be referred to in the rejection).

The teachings of Zhuang and Nagumo are discussed above. The references teach separating the polysaccharides but do not teach using ultrafiltration with the pore sizes claimed by applicant. Sakai teaches using ultrafiltration equipped with hollow fibers to concentrate polysaccharides from seaweed (see column 12, "Referential Example 1"). Thus, it was known in the art at the ultrafiltration can be used successfully to concentrate seaweed polysaccharides. An artisan of ordinary skill would have been motivated to use this known technique and to modify the type of pore size in order to isolate the polysaccharides with the molecular weight's taught by Zhuang in Table II.

18. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhuang and Nagumo as applied to claims 1-4, 14 and 15 above, and further in view of Zvyagintseva et al. (Comparative Biochemistry and Physiology Part C (2000), vol. 126, pp. 209-215).

The teachings of Zhuang and Nagumo are discussed above. The method taught by these references is taught to be useful in extracting polysaccharides such as fucoidan. However, the references do not specifically teach using the method to extract polysaccharides from *Fucus evanescens*. Zvyagintseva teaches that *F. evanescens* contains fucoidan (see abstract). Thus, an artisan of ordinary skill would have reasonably expected that *F. evanescens* could have been used as the seaweed extracted in the method of extracting fucoidan taught by Zhuang and Nagumo. This reasonable expectation of success would have motivated the artisan to modify the method of Zhuang and Nagumo to use *F. evanescens* as the seaweed to extract.

19. No claims are allowed. However, claims 5-13, 17, 18, 23 and 24 are considered to be free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655